

### REMARKS

Claims 1-18 are pending in the application upon entry of amendments. Claims 1-18 have been amended to better conform to U.S. patent practice. Favorable reconsideration in light of the amendments and the remarks which follow is respectfully requested. The Applicants gratefully acknowledge the withdrawal of the previously raised 35 U.S.C § 112/101 rejections, the 35 U.S.C § 102 rejection, and the double patenting rejection.

#### The Amendments

The amendments address several grammatical concerns. Claim 1 has been amended to delete references to associated diseases and to recite "idiopathic pulmonary fibrosis." Support for the amendment can be found, for example, on page 1, lines 4-6 and page 5, lines 26-29.

#### The Enablement Rejection

Claims 1-18 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In stating the enablement rejection, the Examiner relies on the factors described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1998). The Examiner's findings of fact include that current knowledge does not indicate that the inhibition of dendritic cell maturation can be used to treat panbronchitis (Office Action, p. 5, ¶¶ 7-8 citing Todate et al, *Am. J. Rep. Crit. Care Med.*, **2000**, 162, 148-53).

As a further basis for the rejection, the Examiner states that the Application does not present working examples of activity *in vivo* or in art-recognized models of idiopathic pulmonary disease/fibrosis (Office Action, p. 4, no. 11). As such, the Examiner concludes that undue experimentation would be required to practice the invention.

Claim 1 has been amended to remove reference to diseases associated directly or indirectly with idiopathic pulmonary disease, hypersensitive pneumonia and diffused panbronchitis. Therefore, the enablement rejection concerning such related diseases is moot.

The stated logic for the rejection relies on inhibition of maturation of dendritic cells not bearing a predictive relationship to treatment of interstitial lung disorders. The declaration by the applicant, Dorian Bevec, accompanying this paper presents evidence establishing that inhibition of maturation of dendritic cells is predictive and correlated to treatment of interstitial lung disorders. MPEP § 2164.02 discusses the permissibility of correlation between a model assay and claimed methods of use for enablement purposes without the requirement for actual clinical working examples. In general, working examples are not required for enablement, but are only a factor to be considered. Specifically, the declaration of Dorian Bevec states that targeting of dendritic cell maturation as a therapeutic method has been suggested by others skilled in the art, for example, Marchal-Somme et al, *J. Immunology*, **2006**, 176, 5735, 5738 (stating that “novel therapeutic strategies should . . . target mature DC [dendritic cells]”). That is, disablement or prevention of maturation of dendritic cells is known in the art as a predicted avenue of treatment for the diseases at issue, and has been so stated in peer-reviewed journals. The declaration also states the reasons why Todate et al, cited by the Examiner, supports targeting of maturation of dendritic cells as a therapeutic method and presents evidence from *in vivo* human treatment.

Therefore, the assays describing inhibition of maturation of dendritic cells in the Application fully enable the claimed therapeutic methods. That is, the results from dendritic cell inhibition assays fully teach those skilled in the art how to make and use the invention to treat interstitial lung diseases. It is respectfully requested that the rejection of claims 1-18 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Should the Examiner believe that a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-1063.

Respectfully submitted,

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